REMARKS

Entry of the foregoing amendment is respectfully requested, inasmuch as it places various claims in condition for allowance, by eliminating objected to language from claims 5 and 8, and canceling three rejected claims, thus focusing the issues on method claim 17.

Accordingly, the only issue outstanding in the office action of December 30, 2009, is the rejection under 35 U.S.C. 112, first paragraph, of claim 17 as lacking enablement. Reconsideration of this rejection, in view of the following discussion, is respectfully requested.

A proper analysis of enablement clearly leads to the conclusion that claim 17 satisfys the statute. First, at page 2, lines 10 - 17, it is taught that the compounds of formula I inhibit factor Xa, VIIa and IXa, and this statement is supported at page 3, lines 21-22 and page 3, lines 30 – page 4, line 26, with a discussion of the methods used to determine this activity in the subject compounds. At this portion of the specification, it is taught that the compounds thus are useful to treat thromboembolic diseases, such as thrombosis, myocardial infarction, arteriosclerosis, inflammation, apoplexy, angina pectoris, restenosis after angioplasty and claudicatio intermittens. At page 4, lines 29 – 35 and page 5, lines 1-7, it is taught that factor VIIa inhibitors also inhibit the growth of tumor cells and may furthermore be used for tumor therapy. This discussion, *without more*, is sufficient to establish utility of the application for purposes of §112 of the statute, as it constitutes a scientifically supportable statement of utility which would be plausible to one of ordinary skill in the art. Moreover, it is well established that an unsupported suggestion that reactants within a class defined by claims in a typical method of use application would not work, or that such claims embrace inoperative members, insufficient basis alone for rejecting the claims. See *Ex parte Janin*, 209 U.S.P.Q. 761 (POBA 1979). It is clear that these recitations in an Applicant's specification *must* be taken by the PTO as an assertion that all compounds encompassed in the claims are operative in the invention, in the absence of reasons or evidence to the contrary. *In re Marzocchi*, 439 F.2d 220, 169 U.S.P.Q. 367 (CCPA 1971). The first paragraph of 35 U.S.C §112 requires only *objective* enablement. Where a specification teaches the manner and process of making and using the invention, the specification *must* be taken as sufficient under §112, unless there is reason to doubt the truth of these statements. See *Marzocchi*, supra. Applicants' specification clearly enables one to

make and use the disclosed compounds in the claimed methods, as evidenced from the disclosure at page 5 - 7 setting forth pharmaceutical formulations and dosages and the examples which also detail the production of a pharmaceutical formulations.

It is submitted that the Examiner has not provided any such reasons or evidence to doubt the assertion of utility in the specification and, thus, the further steps of the analysis as set forth in *Marzocchi* are not reached. At page 4, it is argued that "the real potential of factor Xa inhibitors is still to be validated in comprehensive clinical trials." This, of course, does not support a rejection of enablement since, as well established, the USPTO is not the FDA and cannot require validation by clinical trials to support enablement. The theory put forth at page 4 of the office action that Xa agents have "unresolved issues" and "are expected to be much less antithrombotically effective" under certain circumstances, again, goes to ethicacy, not utility or enablement.

In counterpoint to the unfounded speculation at page 4 of the office action, the specification, contrary to the argument at page 5 of the office action, does provide a causal link between inhibitory activity of the compounds and treatment of thrombosis. First, it is stated that the compound are inhibitors of coagulation factors VIIa, IXa and thrombin in the blood coagulation cascade. This, alone, is sufficient to establish enablement, as the USPTO has not provided reasons or evidence why this is not true. In particular, no reasons or evidence have been provided other than that allegation noted above that factor Xa inhibition may not be as efficacious as apparently is desired. Moreover, comparable compounds are noted in the specification as having antithrombotic action. See page 2, lines 24-30. It is submitted that this, alone, is sufficient to establish enablement for purposes of patentability, and withdrawal of the rejection under 35 U.S.C. 112 is respectfully requested.

The Commissioner is hereby authorized to charge any fees associated with this response or credit any overpayment to Deposit Account No. 13-3402.

Respectfully submitted,

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